

REMARKS

Claim Rejections Under Non-Statutory Obviousness-Type Double Patenting

Claims 1-24 in the present application stand rejected in the Office Action for non-statutory obviousness-type double patenting over claims 1-20 of co-pending application No. 10/675672 (U.S. Publication No. 2005/0071463), and in light of co-pending applications 10/692417 (U.S. Publication No. 2005/0108405) and 10/651724 (U.S. Publication No. 2005/0050137). Applicants in response have submitted terminal disclaimers, thereby curing the rejections for double patenting and placing claims 1-24 in condition for allowance.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-24 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Office Action takes the position that “the network” recited in claims 1, 9, and 17 lacks antecedent basis. Applicants accordingly have amended claims 1, 9, and 17 to recite “~~the~~a network.” Claims 1, 9, and 17 are therefore patentable. Applicants respectfully submit that these amendments add no new matter to the specification and request reconsideration of claims 1-24.

Claim Rejections Under 35 U.S.C. § 102 Over Cho

Claims 1-24 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Cho, *et al.* (U.S. Patent No. 7,160,252) (hereafter ‘Cho’). “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Independent claim 1 of the present application, as currently amended, claims:

1. A method for creating a user metric pattern, the method comprising:

receiving, within ~~the~~a network, a plurality of disparate user metrics;

saving the plurality of disparate user metrics;

identifying a subset of the saved disparate user metrics that comprise a user metric pattern; and

storing the subset of the saved disparate user metrics as a user metric pattern.

As explained in more detail below, Cho does not disclose each and every element of claim 1, and Cho therefore cannot be said to anticipate the claims of the present application within the meaning of 35 U.S.C. § 102(e). Applicants respectfully traverse each rejection individually and request reconsideration of claims 1-24.

**Cho Does Not Disclose Receiving, Within The
Network, A Plurality Of Disparate User Metrics**

The Office Action takes the position that Cho at column 3, lines 23-24, column 4, lines 60-67; column 6, lines 20-37, and column 7, lines 1-23, discloses the first element of claim 1 as currently amended: receiving, within a network, a plurality of disparate user metrics. Applicants respectfully note in response, however, that what Cho at column 3, lines 23-24, in fact discloses is:

Digitized signal data is provided as input to a respiratory disturbance detection algorithm.

In addition, what Cho at column 4, lines 60-67, in fact discloses is:

As will be described, the IMD is provided for processing and/or storing sensed signal data. A physiological signal received may be a thoracic impedance measurement from which tidal volume and respiration rate may be determined for calculating minute ventilation. A physiological signal may alternatively be an ECG, EGM, blood pressure, activity sensor, oximeter or other sensor signal that includes variations due to the respiratory cycle.

In addition, what Cho at column 6, lines 20-37, in fact discloses is:

FIG. 3 is a flow chart providing additional details regarding methods for determining metrics of respiratory disturbances in one embodiment of the present invention. Upon detecting a respiratory disturbance, it may be desirable to determine various metrics of the disturbance in order to assess the severity of the disturbance and/or track changes in these metrics over time as a way of assessing relative improvement or worsening of the associated pathological condition. In method 200, an impedance signal input is received at step 205 and used for determining minute ventilation, at step 210, based on derived tidal volume and respiration rate. At step 215, the minute ventilation ("MV" in FIG. 3) (or alternatively the derived tidal volume or respiration rate) is compared to a predetermined apnea detection threshold and hyperpnea detection threshold. If a threshold crossing is detected, a respiratory disturbance is detected at step 220, and the time of the onset of the disturbance is flagged at step 225.

And what Cho at column 7, lines 1-23, in fact discloses is:

FIG. 4A is a flow chart summarizing steps included in an alternative embodiment of a method for monitoring for respiratory disturbances. Alternative embodiments may detect pathologic breathing patterns by determining a patient's respiration rate from any physiological signal that includes variations due to the influence of inspiration and expiration. At step 305, a physiological signal input is received. A physiological signal that includes respiration related variations may be, but is not limited to, an ECG signal, an EGM signal, a blood pressure signal, an activity sensor signal, heart sounds, or an oxygen saturation signal. Various implantable sensors are known for use with implantable medical devices. Examples of implantable sensors that are believed to be appropriate for use with the present invention for deriving respiration parameters are: an absolute blood pressure sensor as generally disclosed in U.S. Pat. No. 6,024,704 issued to Meador et al. or U.S. Pat. No. 5,535,752 issued to Halperin et al.; a piezoelectric activity sensor as generally disclosed in U.S. Pat. No.

4,485,813 issued to Anderson et al.; and an oxygen sensor generally disclosed in U.S. Pat. No. 6,162,180 issued to Miesel et al., all of which patents are incorporated herein by reference in their entirety.

That is, Cho at column 3, lines 23-24, column 4, lines 60-67; column 6, lines 20-37, and column 7, lines 1-23, discloses receiving a single digitized physiological signal that is used to detect respiration parameters. Cho discloses multiple user metrics, thoracic impedance, ECG, EGM, and so on, but Cho discloses monitoring these metrics only one at a time, as a single digitized physiological signal, not as a plurality of disparate user metrics as claimed here. Cho's receiving a single digitized physiological signal that is used to determine respiration parameters does not, therefore, disclose receiving, within a network, a plurality of disparate user metrics as claimed in the present application. Not disclosing the first element of claim 1, Cho does not disclose each and every limitation of Applicants' claims. Not disclosing each and every limitation of Applicants' claims, Cho does not anticipate Applicants' claims, and the rejections under 35 U.S.C. § 102(e) should be withdrawn.

**Cho Does Not Disclose Identifying A Subset
Of The Saved Disparate User Metrics That
Comprise A User Metric Pattern**

The Office Action takes the position that Cho at column 3, lines 24-27 and 39-41, column 5, lines 12-19, column 5, line 56 through column 6, line 8, column 6, lines 50-64, and column 9, lines 11-26, discloses the third element of claim 1: identifying a subset of the saved disparate user metrics that comprise a user metric pattern. Applicants respectfully note in response, however, that what Cho at column 3, lines 24-27 and 39-41, in fact discloses is:

The detection algorithm detects a respiratory disturbance when measured respiration parameters meet predetermined detection criteria such as an apnea or hyponea threshold.

...

Metrics of detected respiratory disturbances may be made and tracked over time to monitor worsening or improvement of the disordered breathing condition.

In addition, what Cho at column 5, lines 12-19, in fact discloses is:

At decision step 115, the respiration parameters determined at step 110 are compared to predetermined criteria for detecting a respiratory disturbance. Such criteria may include at least a respiration rate or minute ventilation criterion such that when the respiration rate or minute ventilation is less than or greater than a normal range or crosses a detection threshold, a respiratory disturbance is detected at decision step 115.

In addition, what Cho at column 5, line 56 through column 6, line 8, in fact discloses is:

At decision step 165, one or more predetermined criterion for detecting a respiratory disturbance are applied to the calculated minute ventilation (MV), and/or the measured tidal volume and/or respiration rate. Predetermined criteria may include comparing a given respiration parameter to a minimum or maximum threshold. If criteria for determining a respiratory disturbance are not satisfied, the method 150 returns to step 155 to continue monitoring the impedance signal. If detection criteria are met at step 165, a respiratory disturbance is detected at step 170.

Measurements of the disturbance may then be made, preferably including at least the duration of the disturbance as indicated at step 175. The duration of the disturbance may be an apnea/hypopnea length or hyperpnea length determined as the number of device clock or timer cycles during which corresponding detection criteria are satisfied. The duration is stored at step 175, preferably along with a time and date label to indicate when the detection was made. At step 180, a counter for tracking the number of detected respiratory disturbance episodes is increased by one.

In addition, what Cho at column 6, lines 50-64, in fact discloses is:

At step 245, method 200 determines if a previous apnea episode has been recently detected, which could indicate the presence of a repetitive breathing pattern. Repetitive apnea-hyperpnea or hypopnea-hyperpnea alternation is typical of certain pathological breathing patterns such as sleep apnea and Cheyne-Stokes breathing. If decision step 245 is affirmative, a periodic breathing cycle length is determined and stored at

step 250 as the time between the onset of two consecutively detected apnea episodes. At step 255, a respiratory disturbance episode counter may be increased by one for each disturbance detected. Depending on the type of pathological breathing pattern being monitored, a disturbance that would increase the episode counter may be a single apnea, hypopnea, or hyperpnea event or may be a complete apnea-hyperpnea or hypopnea-hyperpnea cycle.

And what Cho at column 9, lines 11-26, in fact discloses is:

Trends of these periodic breathing metrics are determined and stored at step 420 such that, at step 425, a change in cardiac output may be estimated based on respiratory disturbance metrics and/or circulatory delay time. At step 430, the estimated cardiac output change and periodic breathing metrics are stored, preferably in a histogram format. These data may be displayed for review by a physician such that worsening or improvement in cardiac condition can be observed. Thus, detection and evaluation of disordered breathing patterns may be used for assessing a patient's cardiac condition. If method 400 is implemented in an implantable device capable of delivering a heart failure therapy, a worsening or improvement in cardiac output, determined at step 425, may optionally automatically trigger an appropriate delivery, withholding, or adjustment of therapy at step 435.

That is, Cho at column 3, lines 24-27 and 39-41, column 5, lines 12-19, column 5, line 56 through column 6, line 8, column 6, lines 50-64, and column 9, lines 11-26, discloses comparing periodic breathing metrics to predetermined criteria typical of certain pathological breathing patterns, such as repetitive apnea-hyperpnea, or hypopnea-hyperpnea alternation, in order to determine a breathing pattern. Cho's comparing periodic breathing metrics to predetermined criteria to detect a breathing pattern does not disclose, however, identifying a subset of the saved disparate user metrics that comprise a user metric pattern as claimed in the present application because Cho does not disclose a user metric pattern as claimed in the present application. Cho's entire attention is to infer a present breathing pattern in dependence upon comparisons of present data with predetermined criteria. Cho absolutely does not make any attempt whatsoever to infer user metric patterns from saved data, from saved disparate user metrics as claimed in the present application. The mere fact that Cho uses the word "pattern" to describe pathological breathing does not mean that Cho's breathing patterns disclose user metric

patterns as claimed here. On the contrary, Cho's breathing patterns are present physiological processes, not user metric patterns identified from historical, saved disparate user metrics as claimed in the present application. Not disclosing the third element of claim 1, Cho does not disclose each and every element and limitation of Applicants' claims. Not disclosing each and every element and limitation of Applicants' claims, Cho does not anticipate Applicants' claims, and the rejections under 35 U.S.C. § 102(e) should be withdrawn.

**Cho Does Not Disclose Storing The Subset Of The Saved
Disparate User Metrics As A User Metric Pattern**

The Office Action takes the position that Cho at column 3, lines 27-32, and column 5, lines 20-26, discloses the fourth element of claim 1: storing the subset of the saved disparate user metrics as a user metric pattern. Applicants respectfully note in response, however, that what Cho at column 3, lines 27-32, in fact discloses is:

The detection algorithm may be implemented in the internal device, which may respond to a respiratory disturbance detection by delivering a therapy or collecting and storing physiological data relating to the respiration signal and/or other physiological signals sensed by the implanted device.

And what Cho at column 5, lines 20-26, in fact discloses is:

At step 120, measurements of the respiratory disturbance are determined and stored. Such measurements preferably include at least the duration of the disturbance. At step 125, detection of the respiratory disturbance may optionally trigger a warning to medical personnel, the delivery of a therapy, and/or the storage of physiological data in the implanted device.

That is, Cho at column 3, lines 27-32, and column 5, lines 20-26, discloses storing measurements of a respiratory disturbance. Cho's storing measurements of a respiratory disturbance does not disclose storing the subset of the saved disparate user metrics as a user metric pattern as claimed in the present application. The stored user metric pattern claimed here is a user metric pattern that is identified from a subset of saved disparate user metrics. Cho's stored measurements of a respiratory disturbance are stored

measurements of a present physiological process, not a pattern identified from saved disparate user metrics as claimed here. Not disclosing the fourth element of claim 1, Cho does not disclose each and every element and limitation of Applicants' claims. Not disclosing each and every element and limitation of Applicants' claims, Cho does not anticipate Applicants' claims, and the rejections under 35 U.S.C. § 102(e) should be withdrawn.

Relations Among Claims

Independent claim 1 claims method aspects of creating a user metric pattern according to embodiments of the present invention. Independent claims 9 and 17 respectively claim system and computer program product aspects of creating a user metric pattern according to embodiments of the present invention. For the same reason that Cho does not disclose a method for creating a user metric pattern, therefore, Cho also does not disclose either a system or a computer program product for creating a user metric pattern corresponding to independent claims 9 and 17. Independent claims 9 and 17 are therefore patentable and should be allowed.

Claims 2-8, 10-16, and 18-24 depend respectively from independent claims 1, 9, and 17. Each dependent claim includes all of the limitations of the independent claim from which it depends. Because Cho does not disclose each and every element of the independent claims, Cho does not disclose each and every element of the dependent claims of the present application. As such, claims 2-8, 10-16, and 18-24 are also patentable and should be allowed.

Conclusion

Claims 1-24 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants have amended claims 1, 9, and 17 to cure the rejection. Claims 1, 9, and 17 are therefore patentable. Applicants respectfully

submit that these amendments add no new matter to the specification and request reconsideration of claims 1-24.

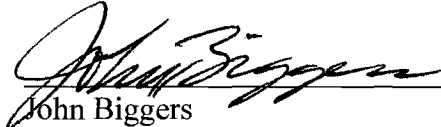
Claims 1-24 stand rejected under 35 U.S.C. § 102 as being anticipated by Cho. Cho does not disclose each and every element of Applicants' claims. Cho therefore does not anticipate Applicants' claims. Claims 1-24 are therefore patentable and should be allowed. Applicants respectfully request reconsideration of claims 1-24.

The Commissioner is hereby authorized to charge or credit Deposit Account No. 09-0447 for any fees required or overpaid.

Respectfully submitted,

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By:



John Biggers

Reg. No. 44,537

Biggers & Ohanian, LLP

P.O. Box 1469

Austin, Texas 78767-1469

Tel. (512) 472-9881

Fax (512) 472-9887

ATTORNEY FOR APPLICANTS